

REMARKS

In the outstanding Office Action, the Examiner has noted an informality in the Specification. The Examiner has objected to an informality in claim 13. The Examiner has rejected claims 1-31, 35-39, 42, and 45-50 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,951,503, issued in the name of Pomatto, (hereinafter "Pomatto"). The Examiner has rejected claims 1-31, 35-39, 42, and 44-50 under 35 U.S.C. §102(b) as being anticipated United States Patent No. 4,776,324, issued in the name of Clarren, (hereinafter "Clarren"). The Examiner has rejected claims 32-34 under 35 U.S.C. §103(a) as being unpatentable over Pomatto in view of United States Patent No. 6,381,760, issued in the names of Lampe et al., (hereinafter "Lampe"). The Examiner has indicated that claims 40, 41 and 43 would be allowable if rewritten in independent form to include all of the limitations of the respective base claims and any intervening claims.

Claims 1-50 were originally presented for examination. Claims 1, 10, 13, 17, 24, 42, and 45 have been amended by way of the present Response. No new matter has been added by way of the present Response. Claims 1-50 are currently pending, of which, claims 1, 10, 17, 24, 42, and 45 are in independent form. Favorable reconsideration of the present Response as currently constituted is respectfully requested.

Allowable Claims

Applicant gratefully acknowledges the indication by the Examiner that claims 40-41 and 43 would be allowable if rewritten in independent form to include all of the limitations of the respective base claims and any intervening claims. Applicant respectfully submits that in view of the foregoing amendments and following remarks, claims 1-50, including allowable claims 40-41 and 43, are allowable as subject matter from the allowable claims has been integrated into each of the independent claims; namely, claims 1, 10, 17, 24, 42, and 45. In particular, the independent claims have been amended to include limitations directed to the interior surface of the protective shell being operable to accommodate infant head growth.

Specification Informality

Applicant has amended paragraph 41 of the Specification to cure the informality as required by the Examiner. Withdrawal of the outstanding informality objection to the Specification is respectfully requested.

Claim Objection

Applicant has amended claim 13 to cure an error of a typographical nature as required by the Examiner. Withdrawal of the outstanding claim objection is respectfully requested.

Rejections Under 35 U.S.C. §102(b)

Claims 1-31, 35-39, 42, and 45-50 stand rejected under 35 U.S.C. §102(b) as being anticipated by Pomatto. The present invention, as defined by amended claim 1, is directed to a cranial orthosis for preventing positional plagiocephaly in infants. The cranial orthosis provides a close, non-interfering fit with the infant's head so that positional plagiocephaly, a flattening deformity sometimes referred to as the "bean bag" effect, is prevented. In particular, the cranial orthosis includes a protective shell having an interior surface that is conformed in shape to the surface curvature of a normal infant cranium and is operable to **accommodate infant head growth**.

Applicant respectfully submits that Pomatto does not anticipate or suggest Applicant's present invention as defined by claim 1. Pomatto discloses a cranial orthosis band. With reference to figures 5 through 10 of Pomatto, a cranial orthosis band 11 is employed to either remodel an abnormal cranium by allowing growth of the cranium to a natural symmetrical generally rounded shape or prevent inducement of a deformity. Contrary to amended claim 1, the cranial orthosis band 11 of Pomatto is not operable to accommodate infant head growth. The orthosis band 11 is custom manufactured to fit the individual infant and comprises an outer layer 16 of co-polymer polypropylene material having a thickness of 3/16 inch (4.76 mm) and a liner of medium density sheet polyurethane foam that is 3/8 inch (10 mm) thick. Hence, the orthosis band 11 has a total thickness of 14.76 mm.

As noted in paragraphs 45-48 of Applicant's specification, the infant mean head circumference grows during the first eighteen months of age from about 34 cm to about

48 cm for boys and from about 34 cm to about 47 cm for girls. This is a total growth of approximately 14 cm or 140 mm, which is ten times larger than the total 14.76 mm thickness of the orthosis band of Pomatto. The orthosis band of Pomatto is uniquely sized to match a particular infant's head and is not designed to expand in size to accommodate growth of the infants head. In fact, if the orthosis band of Pomatto were to be placed on an infant's head and not removed, Pomatto's fixed-size orthosis band would retard and oppose normal growth and cranial expansion.

The orthosis band of Pomatto is custom manufactured to fit a particular infant of a particular age and head size. Pomatto describes this manufacturing process as follows:

The orthosis band 11 shown in the drawings is custom manufactured to fit the individual patient.

In one method for fabricating the orthosis band, a negative mold of the patient's head is formed. From the negative mold of the head, a positive model of the head is cast. For orthosis bands which are being used only to prevent the occurrence of abnormality rather than for remodeling, the orthosis band may be fabricated directly from the positive model. In those applications of the orthosis band intended to correct abnormalities, the positive model is shaped to account for the remodeling which is required to correct abnormalities as well as the patient's cranial growth. The resultant positive model is then employed to shape an orthosis band 11.

To fabricate the orthosis band, liner material 17 is vacuum formed over the model. The outer layer material 16 is then vacuum formed over the positive model. The model is removed from this structure, trim lines are applied, and the structure is trimmed in accordance with the trim lines to the desired configuration illustrated in the drawing and described above. Column 4, line 66 through column 5, line 19.

Therefore, Pomatto neither anticipates nor suggests Applicant's invention since contrary to Applicant's amended claim 1, the orthosis band of Pomatto is not designed to expand in size to accommodate growth of an infant's head. Accordingly, Applicant respectfully requests withdrawal of the outstanding §102(b) rejection and allowance of claim 1.

Claims 2-9 depend from claim 1 and add further limitations. Accordingly, Applicant respectfully requests withdrawal of the outstanding §102(b) rejection and allowance of claims 2-9.

Independent claims 10, 17, and 24, as amended, are directed to embodiments of a cranial orthosis for preventing positional plagiocephaly in infants. Similar to claim 1, claims 10, 17, and 24 each include limitations to an interior surface that is operable to accommodate infant head growth. Accordingly, for the reasons presented herein, withdrawal of the outstanding §102(b) rejection and allowance of claims 10, 17, and 24 are respectfully requested.

Claims 11-16 depend from claim 10 and add further limitations; claims 18-23 depend from claim 17 and add further limitations; and claims 25-31 and 35-39 depend from claim 24 and add further limitations. Accordingly, in view of the foregoing, withdrawal of the outstanding §102(b) rejection and allowance of claims 11-16, 18-23, 25-31, and 35-39 are respectfully requested.

Independent claims 42 and 45, as amended, are directed to embodiments of a method for preventing postural plagiocephaly in a human infant. Similar to claim 1, claims 42 and 45 each include limitations to an interior surface that is operable to

accommodate infant head growth. Accordingly, for the reasons presented herein, withdrawal of the outstanding §102(b) rejection and allowance of claims 42 and 45 are respectfully requested.

Claims 46-50 depend from claim 45 and add further limitations. Accordingly, in view of the foregoing, withdrawal of the outstanding §102(b) rejection and allowance of claims 46-50 are respectfully requested.

Claims 1-31, 35-38, 42, and 44-50 stand rejected under 35 U.S.C. §102(b) as being anticipated Clarren. As discussed herein, each of Applicant's independent claims, i.e., claims 1, 10, 17, 24, 42, and 45, as amended, include limitations directed to a cranial orthosis including an interior surface that is operable to accommodate infant head growth.

Applicant respectfully submits that Clarren does not anticipate or suggest Applicant's present invention. Clarren discloses a graded series of therapeutic and protective infant helmets that are utilized to treat an infant that is already suffering from a cranial abnormality, for example deformational cranial asymmetry. The graded series of sized helmets are each designed for an infant of a specified age and degree of plagiocephaly. This is contrary to Applicant's claimed invention which includes a single cranial orthosis that is intended for use as a preventative measure by a healthy infant that has a normal cranium and is operable to accommodate normal infant head growth. Moreover, Applicant's claimed invention is directed to preventing positional plagiocephaly in normal, healthy infants having complaint, developing head areas to

protect and is not directed to treating infants who already have deformational cranial asymmetry, as taught by Clarren.

Clarren describes the graded series of sized helmets for treating deformational cranial asymmetry as follows:

The invention provides, in one aspect, a method of helmet treatment for deformational cranial asymmetry in which the dimensions of the therapeutic helmet cavity are prescribed in relation to specific CT scan sections of the infant's cranium. **A graded series of sized helmets is provided for such treatments. Each helmet cavity is configured to accommodate and effectively treat infants of specified ages and degrees of plagiocephaly.** By employing the subject off-the-shelf helmets, the time-consuming and labor-intensive fitting of individualized helmet is obviated. Furthermore, since the subject helmets are prescribed on the basis of data generated from standard CT scans, the attending physician can prescribe and order a suitable helmet, from a location remote from the helmet manufacturer or distributor, with relatively minor inconvenience and expense to the patient and patient's family. **Emphasis added.** Column 3, line 58 through column 4, line 6.

Hence, similar to Pomatto, Clarren does not disclose a single cranial orthosis that is operable to accommodate head growth in a normal, health infant. Rather, Clarren discloses a graded series of helmets to accommodate head growth in infants who already have a cranial abnormality that needs to be corrected. Accordingly, Clarren neither anticipates nor suggests Applicant's claimed invention. Applicant respectfully requests withdrawal of the outstanding §102(b) rejection and allowance of independent claims 1, 10, 17, 24, 42, and 45.

Claims 1-9 depend from claim 1 and add further limitations; 11-16 depend from claim 10 and add further limitations; claims 18-23 depend from claim 17 and add further limitations; claims 25-31 and 35-39 depend from claim 24 and add further

limitations; claim 44 depends from claim 42 and adds further limitations; and claims 46-50 depend from claim 45 and add further limitations. Accordingly, Applicant respectfully requests withdrawal of the outstanding §102(b) rejection and allowance of claims 1-9, 11-16, 18-23, 25-31, 35-39, 44, and 46-50.

Rejection Under 35 U.S.C. §103(a)

Claims 32-34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pomatto in view of Lampe. Lampe is not properly combinable with Pomatto to support an obviousness rejection of claims 32-34 for the following reasons. Lampe discloses a soccer helmet having a flexible exterior shell and a layer of stretchable fabric secured to an inside surface portion of the flexible shell, for compressively engaging about the head. In one embodiment, the exterior shell is said to be formed in front and rear panel sections 2,3, and the sections are movably coupled together by a pair of stretchable adjustment straps 7 (Fig. 19), which hold the shell in tight compressive engagement onto the head.

Other embodiments disclosed by Lampe show the shell offset from the head, coupled by straps of stretchable fabric to an elastic headband which is configured for tight compressive engagement about the head, so that the soccer helmet will not fall off when subjected to impact forces. This binding, tight engagement is not suitable for use on the soft, compliant head of a newborn infant, and would exert pressure against the infant's head that could cause a cranial deformity, and would oppose and restrict normal

head growth. Consequently, Lampe's soccer helmet teaches away from the inventive concept, and for this reason is not a proper reference under 35 U.S.C. §103(a).

Moreover, upon entry of the foregoing amendments, claims 32-34 are made dependent from and add limitations to independent claim 24, which has been amended to include an interior surface that is operable to accommodate normal infant head growth. Accordingly, Applicant respectfully requests withdrawal of the outstanding §103(a) rejection and allowance of claims 32-34.

Fee Statement

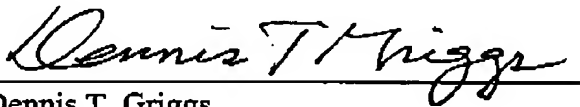
The number of independent claims and the total number of claims remain unchanged by the present amendment. Accordingly, Applicant believes that no fees are due for the filing of this Response. If, however, the Examiner should determine that fees are due, please charge the same to our deposit account (Account No. 07-2156).

CONCLUSION

The Examiner is respectfully requested to carefully consider the foregoing amendments and remarks. A favorable action in the form of an early notice of allowance is respectfully requested. If there are any matters remaining that may be cleared up by interview, please call Applicant's attorney at 972-447-4569.

Respectfully submitted:

Date: February 1, 2005



Dennis T. Griggs
Reg. No. 27,790
Attorney for Applicant

Griggs Bergen LLP
17950 Preston Road, Suite 1000
Dallas, Texas 75252
972-447-4569